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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,415	03/12/2004	Rebecca Guggemos Bakker-Arkema	A0000343-B	7133

28880 7590 08/30/2004

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EXAMINER	
HENLEY III, RAYMOND J	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 08/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/799,415	BAKKER-ARKEMA ET AL.	
	Examiner	Art Unit	
	Raymond J Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/12/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

CLAIMS 1-15 ARE PRESENTED FOR EXAMINATION

Applicants' Preliminary Amendment and Information Disclosure Statement filed March 12, 2004 has been received and entered into the application. Accordingly, the specification at page 1 has been amended. Also, as reflected by the attached, completed copy of form PTO-1449, the cited references have been considered.

Specification

The disclosure is objected to because of the following informality:

In Applicants' Preliminary Amendment, line 1 after "May 9, 2002,", ---now abandoned--- needs to be inserted.

Appropriate correction is required.

Claim Rejection - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7 and 8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating congestive heart failure and other edematous conditions, does not reasonably provide enablement for preventing such failure and conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The burden of enabling the prevention of congestive heart failure and other edematous conditions would be much greater than that of enabling the treatment of congestive heart failure

and other edematous conditions. In the instant case, the specification does not provide guidance as to how one skilled in the art would accomplish the objective of preventing congestive heart failure and other edematous conditions or how a patient could be kept from every being susceptible to these conditions. Nor is there any guidance provided as to a specific protocol to be utilized in order to show the efficacy of the presently claimed active ingredients for congestive heart failure and other edematous conditions.

Specifically, it is highly unlikely, and the Office would require experimental evidence to support the contention that the claim specified active could actually prevent congestive heart failure and other edematous conditions by simply administering, by any method, an amount of the claim specified active agents. The specification fails to enable one of ordinary skill in the art to practice the claimed methods for preventing congestive heart failure and other edematous conditions.

The term "prevention" or "preventing" is synonymous with the term "curing" and both circumscribe methods of treatment having absolute success. Since absolute success is not reasonably possible with most diseases/disorders, especially those having etiologies and pathophysiological manifestations as complex/poorly understood as congestive heart failure and other edematous conditions, the specification, which lacks a showing that congestive heart failure and other edematous conditions could actually be prevented, is viewed as lacking an adequate written description of the same.

The present specification is evaluated by the Examiner as directed by the Court in *In re Marzocchi et al.* , 169 USPQ 367 (CCPA 1971):

"Specification disclosure which contains teaching of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining

subject matter sought to be patented must be taken as in compliance with enabling requirement of first paragraph of 35 U.S.C. 112 *unless there is reason to doubt the objective truth of statements contain therein which must be relied on for enabling support*; assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in specification is truly enabling." (emphasis added).

Here, the objective truth of the statement that congestive heart failure and other edematous conditions could be actually prevented is doubted because the term "prevention" or "preventing" is synonymous with the term "curing" and both circumscribe methods of treatment having absolute success and because absolute success is not reasonably possible with most diseases/disorders.

Accordingly, the claims are deemed properly rejected.

It is suggested that in claim 7, line 1 "preventing and" be deleted in order to overcome this rejection.

Claim Rejection - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 8 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The present claim recites "preventing and treating". However, it is unclear as to how this could be accomplished simultaneously because "preventing" connotes that the person is at risk of developing a disease rather than the presence of the disease whereas "treating" connotes that the

person is presently suffering from the disease. Applicants may wish to consider amending claim 7 to recite "preventing or treating" in order to overcome this ground of rejection.

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) The invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1, 2, 5, 7, 9, 10, 12, 13 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Ellis-Grosse et al. (U.S. Patent No. 6,420,358, cited by the Examiner).

The patentees teach a pharmaceutical composition comprising a benzodiazepine compound designated as "VPA-985" which is indicated to be a vasopressin antagonist (column 7, line 30) and a diuretic compound such as furosemide (column 9, lines 27-30). The compositions are taught to be useful for management of edema, congestive heart failure (column 1, lines 15-18 and 65-67), loss of electrolytes such as sodium and potassium (column 1, line 67 - column 2, line 12).

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellis-Grosse et al., as relied upon above, in view of Tanaka et al. (U.S Patent No. 5,723,606, cited by the Examiner).

The difference between the above and applicants' claimed subject matter lies in that Ellis-Grosse et al. fail to highlight the use of the vasopressin antagonists as represented by the formula of present claim 3, or the specific vasopressin antagonist conivaptan.

However, to the skilled artisan, applicants' claimed subject matter would have been obvious because Tanaka et al. teach compounds of the formula of present claim 3 (column 2, line 11 - column 12, line 26), and specifically conivaptan (column 74, line 1-25) as being effective as vasopressin antagonists (see the abstract) and useful for the management of heart failure, edema (column 28, lines 43, 44 and 49). Accordingly, given the disclosures of Ellis-Grosse et al. and Tanaka et al., the skilled artisan would have recognized that conivaptan could be used as Ellis-Grosse et al. employed their vasopressin antagonist and the skilled artisan would have been motivated to use the compounds of Tanaka et al. in the invention of Ellis-Grosse et al. because like the compound of Ellis-Grosse et al., the compounds of Tanaka et al. were also known as vasopressin antagonists.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Raymond J Henley III
Primary Examiner
Art Unit 1614

August 20, 2004